

Appendix I

TIMELINE OF EVENTS

- July 2001 - Dr. Ali Mokdad approached by Dr. Jeffrey Koplan, Director, CDC, about updating the paper published in 1993 on Actual Causes of Death (McGinnis JM, Foege WH. Aerial causes of death in the United States. *JAMA* 1993;270:2207-12)
- December 2003 - manuscript submitted for clearance authored by Mokdad Ali, Marks JS, Stroup DF was added subsequently to assist with statistical concerns and Gerberding JL added later following conversations with Dr. Marks to provide input on policy and epidemiology.) Process for cross-clearance by other CDC programs initiated at this time.
- February 2004 - manuscript discussed at division directors meeting at the National Center for Chronic Disease Prevention and Health Promotion.
- June 2003 - manuscript submitted to *JAMA* for consideration for publication.
- August 2003 - *JAMA* editors ask for revisions to the manuscript.
- December 2003 - Authors submit revised manuscript to *JAMA*.
- January 2004 - *JAMA* editors ask for additional revisions with 1-week deadline.
- Authors submit revised manuscript and paper accepted for publication on January 26, 2004.
- March 2004 - *Actual causes of death in the United States, 2000* published in *JAMA* with accompanying editorial comments by McGinnis and Foege.
- June 21, 2004 - Letter sent by Congressman Henry Waxman to the Comptroller General address "the concerns in the scientific community about the findings of this important paper".

June 23, 2004 - Five letters to the editor published in *JAMA* commenting on the publication with a response by the three authors (Dr. Gerberding was not available to participate because of scheduling and short turn around required by the journal.)

June 29, 2004 - Briefing of panel of CDC leadership to discuss the Actual Causes of Death methodology and report on internal review conducted by NCCDPHP. It was recommended that an internal review committee be established chaired by Dr. Stephen B. Thacker and staffed by NCCDPHP and that GAO be contacted to ascertain their process to respond to Congressman Waxman. Dr. George Mensah, Acting Director, NCCDPHP, was tasked to contact GAO. Dr. Dixie Snider, Acting Chief of Science, CDC/ATSDR, was designated the point of contact for Dr. Thacker in the Office of the Director, CDC/ATSDR, and was tasked to contact the editors of *JAMA* to inform them of CDC plans.

July 2004 - After discussions with Dr. Mensah GAO agreed with a proposal to expand the CDC committee to include experts in the Department of Health and Human Services outside of CDC and to delay its review pending the report of the CDC committee. Dr. Snider contacted his counterparts at the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services to nominate experts to join the CDC committee.

August 2004 - Committee members selected and provided background materials to review prior to meeting. Planning conference call took place on August 30.

September 2004 - Review Committee meets with CDC scientists with concerns about the methods in the published paper and with the authors of the paper and each member submits an independent report to the Chair, Dr. Thacker.

Attachment K

Clearance recommendations

- There should be a standard, agency-wide electronic clearance tracking system for scientific publications.
- There should be an explicit policy among CIOs for addressing disagreements about clearance, including documentation of the disagreement and how the issues were managed.
- Clearance officials in an organization should not clear manuscripts on which they are authors.
- There should be a policy that addresses authorship by the CDC Director as well as senior managers at other levels of the organization.

Attachment L

Research recommendations

- Examine the effect on population attributable risk (PAR) estimates of using cause-specific vs all cause mortality for various risk factors
- Consider how to incorporate measure beyond mortality (morbidity, years of potential life lost, disability, etc) into PAR estimates to obtain more comprehensive estimates of the effect of specific risk factors
- Examine how adjustment for a number of factors such as interaction among risk factors and confounding affects PAR estimates
- Consider which models are best suited for which subsequent uses of PAR estimates
- Quantify the degree of uncertainty about PAR estimates
- Identify simple but valid approaches for presenting summary estimates in this area; this is a topic for communications science as well as other disciplines
- Develop methods and identify data sources that would enable PAR estimates for diet and physical activity independently of using weight and height data as a proxy for diet and physical activity
- Evaluate the differential effect of using different reference points for estimating PARs (e.g., BMI of 23-25 vs BMI <25)
- Develop models to estimate lag time effects of obesity
- Assess the feasibility of cause-specific deaths rather than overall mortality attributable to obesity

- Develop a more robust model to produce individual estimates for specific behaviors that could be applied to state data using the Behavioral Risk Factor Surveillance System and state mortality data and make this model available to states and other users
- Write a state of the art paper on the health burden associated with smoking, diet, and physical activity using comparable and alternative methods to calculate associated health burden (mortality, morbidity, years of life lost etc).
- Develop a common vocabulary for the terms and methods used to estimate health burden
- Revisit the conceptual model underlying "actual causes" to examine other potential areas such as mental health and child maltreatment
- Address the tension between the need to set policy given limited data and the need for scientific rigor and attempt to produce practical guidelines, including how such policies and procedures are communicated
- Consider institution of an online working paper series in which potential concerns about bias and the detailed underpinnings of published papers could be accessed by interested investigators